## Chapter 246-470 WAC Prescription Monitoring Program (DRAFT RULES) March 8, 2011

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# **NEW SECTION.**

WAC 246-470-001 Purpose. These rules implement the prescription monitoring program, established by the Legislature in chapter 70.225 RCW, as a means to promote the public health and welfare and to detect and prevent prescription drug abuse.

WAC 246-470-010 Definitions. For the purpose of this chapter, the following words and phrases will have the following meanings unless the context clearly indicates otherwise:

- (1) "Controlled substance" has the same meaning provided in RCW 69.50.101.
- (2) "Department" means the Department of Health.
- (3) "Dispenser" means a practitioner or pharmacy that delivers a Schedule II, III, IV, or V controlled substance to the ultimate user, but does not include:
- (a) A practitioner or other authorized person who only administers, as defined in RCW 69.41.010, a controlled substance; or
- (b) A licensed wholesale distributor or manufacturer, as defined in chapter 18.64 RCW, of a controlled substance.
- (4) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for who a drug is dispensed.
- (5) "Patient address" means the current geographic location of the patient's residence. If the patient's address is in care of another person or entity, the address of that person or entity must be provided in its entirety. When alternate addresses are possible, they must be recorded in the following order of preference:
- (i) The geographical location of the residence, as would be identified when a telephone is used to place a 9-1-1 call; or
  - (ii) A post department address issued by the United States Postal Service; or
  - (iii) The common name of the residence and town.
  - (6) "Pharmacist" means a person duly licensed to engage in the practice of pharmacy.
- (7) "Prescriber" means a licensed health care professional with authority to prescribe controlled substances.
- (8) "Prescription monitoring information" means information submitted to and maintained by the program.
- (9) "Program" means the Prescription Monitoring Program established under chapter 70.225 RCW.
  - (10) "Valid photographic identification" means:

- (a) A driver's license or instruction permit issued by any United States state or province of Canada. If the patient's driver's license has expired, he/she must also show a valid temporary driver's license with the expired card.
  - (b) A state identification card issued by any United States state or province of Canada.;
  - (c) An official passport issued by any nation.
- (d) A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.
  - (e) A merchant marine identification card issued by the United States Coast Guard.
- (f) A state liquor control identification card. An official age identification card issued by the liquor control authority of any United States state or Canadian province.
- (g) Enrollment card issued by the governing authority of a federally recognized Indian tribe located in Washington, if the enrollment card incorporates security features comparable to those implemented by the department of licensing for Washington drivers' licenses and are recognized by the liquor control board.

WAC 246-470-020 Adding additional drugs to the program.

(1) The board of pharmacy under RCW <u>70.225.020</u>, may add additional drugs to the list of drugs being monitored by the program by having the department amend these rules.

#### NEW SECTION.

WAC 246-470-030 Data submission requirements for dispensers. Dispensers must provide the dispensing information required by RCW 70.225.020 and this section for all scheduled II, III, IV, V controlled substances and for drugs identified by the board of pharmacy in section 020 of this rule.

(1) Dispenser identification number(s). Dispensers must acquire and maintain an identification number issued to dispensing pharmacies by the National Council for Prescription

Drug Programs or a prescriber identifier issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice.

- (2) Submitting data. Dispensers must submit data to the department electronically, no less than one week from the date of dispensing, and in the format required by the department.
- (a) Dispensers must submit for each dispensing the following information and any additional information required by the department:
  - (i) patient identifier(s) used to identify a particular person by the dispenser;
  - (ii) name of the patient for whom the prescription is ordered including: first name, middle initial, last name, and generational suffixes if any;
  - (iii) patient date of birth;
  - (iv) patient address;
  - (v) patient gender;
  - (vi) drug dispensed;
  - (vii) date of dispensing;
  - (viii) quantity and days supply dispensed;
  - (ix) refill information;
  - (x) prescriber identifier;
  - (xi) prescription issued date and serial number;
  - (xii) dispenser identifier;
  - (xiii) prescription fill date and number and;
  - (xiv) source of payment;
  - (xv) name of person picking up the prescription, as verified by valid photographic identification; and
  - (xvi) for veterinary prescriptions, name of client (animal owner).
- (b) non-resident pharmacies, as defined in RCW 18.64.360, are required to submit only the transactions where the patient has a Washington State zip code.
- (c) Data submission requirements do not apply to the department of corrections or pharmacies operated by a county for the purpose of providing medications to offenders in state or county correctional institutions who are receiving pharmaceutical services from a state or county correctional institution's pharmacy, except that the state or county correctional institution's pharmacy must submit data to the program related to each offender's current

prescriptions for controlled substances upon the offender's release from a state or county correctional institution.

## NEW SECTION.

WAC 246-470-040 Patient access to information from the program.

- (1) A patient, or a patients' personal representative authorized under chapter 11.02 RCW (Probate and trust law), may obtain a report listing all prescription monitoring information that pertains to the patient.
- (a) Procedure for obtaining information. A patient or a patient's personal representative requesting information in (1) of this section must submit a written request in person at the department, or at any other place specified by the department. The written request must be in a format established by the department and must contain at least, but is not limited to, the following elements:
- (i) The patient's full name and the full name of the patient's personal representative, if applicable;
- (ii) The patient's address, and the complete physical address of the patient's personal representative, if applicable;
- (iii) The patient's telephone number, if any, and the telephone number of the personal representative, if applicable; and
  - (iv) The time period for which information is being requested.
- (b) Identification required. The patient or the patient's personal representative must provide valid photographic identification prior to obtaining access to the information requested in (1) of this section.
- (c) Proof of personal representation. Before obtaining access to the information described above, personal representatives must provide either:
  - (i) an official attested copy of the judicial order granting them authority to gain access to the health care records of the patient; or
  - (ii) in the case of parents of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing legal guardianship; or

(iii) in the case of persons holding power of attorney, the original document establishing the power of attorney.

The department may verify the patient authorization by any reasonable means prior to providing the information to the personal representative.

#### NEW SECTION.

WAC 246-470-050 Pharmacist and prescriber access to information from the program. Pharmacists, prescribers, or licensed health care practitioners duly authorized by a prescriber may obtain any prescription monitoring information relating to their patients, for the purpose of providing medical or pharmaceutical care.

- (1) Registration for access. A pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber must register with the department in order to receive an authentication for access by providing the following information to the department:
  - (a) full name;
  - (b) state license number;
  - (c) business address; and
  - (d) other information required by the department
- (2) Verification by the department. The department shall verify the authentication and identity of the pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber before allowing access to any prescription monitoring information
- (3) Procedure for obtaining information. A pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber who seeks access to the information described above may submit a request electronically using the authentication issued by the department or in a manner and format established by the department. A pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber may alternately submit a written request via mail or facsimile transmission in a manner and format established by the department. The request must contain, but is not limited to, the following elements for each patient:
  - (a) The full name and date of birth of the patient;
  - (b) The patient's address(es) and telephone number(s), if known;
  - (c) The time period for which information is being requested;

- (d) The name of the pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber;
- (e) The pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber's authentication; and
- (f) The signature of the pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber.
- (4) Reporting lost or stolen authentication. If the authentication issued by the department is lost, missing, or the security of the authentication is compromised, the pharmacist, prescriber, or licensed health care practitioner duly authorized by a prescriber shall notify the department by telephone and in writing as soon as reasonably possible.
- (5) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

WAC 246-470-060 Law enforcement, prosecutorial officials, coroners, and medical examiners access to information from the program. Local, state, or federal law enforcement officers and prosecutorial officials may obtain any prescription monitoring information as required for a bona fide specific investigation involving a designated person. A local, state, or federal coroner or medical examiner may obtain any prescription monitoring information regarding investigations of deaths.

(1) Procedure for obtaining information. Local, state, or federal law enforcement officers, prosecutorial officials, country coroners and medical examiners who seek access to prescription monitoring information must register with the department. Once registration is approved the requester may submit a request using the authentication provided by the department. The request from a local, state, or federal law enforcement officer and prosecutorial officials shall contain an attestation that the information is required for a bona fide specific investigation involving a designated person. The written request from a local, state, or federal coroner or medical examiner shall contain an attestation that the information is required for determining cause of death in an investigation.

- (2) Reporting lost or stolen authentication. If the authentication issued by the department is lost, missing, or the security of the authentication is compromised, the local, state, and federal law enforcement officers, prosecutorial officials, coroners or medical examiners shall notify the department by telephone and in writing as soon as reasonably possible.
- (3) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

WAC 246-470-070 Health professional licensing, certification, or regulatory agency or entity's access to information from the program. A director, director's designee, compliance officer, or investigator of a health professional licensing, certification or regulatory agency may obtain prescription monitoring information from the program.

- (1) Procedure for obtaining information. A director, director's designee, compliance officer, or investigator of a health professional licensing, certification or regulatory agency or entity must submit a request to the department. The request shall contain a statement of facts from which the department may make a determination of reasonable cause for the request.
- (2) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

## **NEW SECTION.**

WAC 246-470-080 Department of Social and Health Services, Department of Labor and Industries, and Department of Corrections' access to information from the program

- (1) An authorized practitioner of the Department of Social and Health Services may obtain any prescription monitoring information regarding Medicaid program recipients. The information shall be provided in a format established by the department.
- (a) Procedure for obtaining information. An authorized practitioner of the Department of Social and Health Services who seeks access to prescription monitoring information described above must submit a request to the department.

- (2) The director or director's designee of the Department of Labor and Industries may obtain any prescription monitoring information regarding worker's compensation claimants. The information shall be provided in a format established by the department.
- (a) Procedure for obtaining information. The director or director's designee of the Department of Labor and Industries who seeks access to prescription monitoring information described above must submit a request to the department.
- (3) The director or director's designee of the Department of Corrections may obtain any prescription monitoring information regarding offenders committed to the Department of Corrections. The information shall be provided in a format established by the department.
- (a) Procedure for obtaining information. The director or director's designee of the Department of Corrections who seeks access to prescription monitoring information described above must submit a request to the department.
- (4) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

WAC 246-470-090 Other states' prescription monitoring program access to information from the program. States with an established prescription monitoring program may obtain any prescription monitoring information for requests from within their state that do not violate the provisions of this chapter or chapter 70.225 RCW.

- (1) Procedure for obtaining information. Another state prescription monitoring program seeking access to prescription monitoring information must first establish a data sharing agreement (inter-state compact) with the department. The agreement will specify what information may be made available to what individuals or organizations, how requests are to be made, how quickly requests should be processed, and the format the information should be provided in.
- (2) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

#### NEW SECTION.

WAC 246-470-100 Public or private research entities' access to information from the program. Any public or private entity may obtain any prescription monitoring information after the department removes information that could be used to identify individual patients, dispensers, prescribers, and persons who received prescriptions from dispensers. The information shall be provided in a format established by the department.

- (1) Procedure for obtaining information. Any pubic or private entity who seeks access to prescription monitoring information described above must submit a written request via mail, facsimile transmission, or by electronic means. The written request shall contain a statement of facts from which the department may make a determination of reasonable cause for the request.
- (2) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must match the intent as outlined in RCW 70.225.040 and this section.

## **NEW SECTION.**

WAC 246-470-110 Confidentiality.

(1) Pursuant to RCW 70.225.040, prescription monitoring information is confidential in accordance with chapter 70.02 RCW and federal health care information privacy requirements.

## **NEW SECTION.**

WAC 246-470-120 Penalties and Sanctions.

- (1) A person who intentionally or knowingly uses or discloses prescription monitoring information in violation of chapter 70.225 RCW is subject to civil penalty.
- (2) A dispenser or practitioner acting in good faith is immune from any civil, criminal, or administrative liability for requesting, receiving, or using information from the program in accordance with RCW 70.225.240.

- (3) A dispenser who knowingly fails to submit prescription monitoring information to the Department as required by these rules and by statute is subject to disciplinary action under chapter 18.130 RCW.
- (4) If the department determines a person has intentionally or knowingly used or disclosed prescription monitoring information in violation of chapter 70.225 RCW the following action(s) may be taken by the department:
  - (a) Terminate access to prescription monitoring information.
  - (b) File a complaint(s) with the appropriate health licensing and credentialing entities.
  - (c) Report violation(s) to law enforcement.